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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,357	10/31/2001	Jerome T. Hartlaub	11738.00045	2290
27581	7590	03/23/2004	EXAMINER	
MEDTRONIC, INC.			LAU, TUNG S	
710 MEDTRONIC PARKWAY NE			ART UNIT	
MS-LC340			PAPER NUMBER	
MINNEAPOLIS, MN 55432-5604			2863	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/001,357		HARTLAUB, JEROME T.	
	Examiner		Art Unit	
	Tung S Lau		2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 19-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 12, 15, 16 and 18 is/are rejected.
- 7) ☒ Claim(s) 2, 4-8, 13, 14, 17 and 26-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4, 8, 9</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Claims 9-11, 19, 21-25, 20 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected without traverse invention as noted in paper number 10.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

a. Claims 1, 3, 15, 16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (U.S. Patent 5,188,106) in view of Wojcicki et al. (U.S. Patent 5,190,522).

Regarding claim 1:

Nappholz discloses a computing device in communication with an implantable drug delivery device for delivering at least one drug to a patient, the drug delivery device having a reservoir containing at least one drug and a nonconformance monitor module configured to monitor at least one performance parameter, the computing device comprising in combination: (a) a memory having stored therein pump performance acquisition instructions (Col. 29, Lines 24-67); (b) a telemetry module (fig. 10, unit 103) providing bi-directional communication between the computing device and the implantable drug delivery device and providing the

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pump performance acquisition instructions to the implantable drug delivery device and receiving pump performance data from the implantable drug delivery device (fig. 10, unit 110, 102, 115, 120, Col. 33, Lines 42-56).

Regarding claims 3, 15, 16, 18:

Nappholz discloses the memory includes the patient performance requirement information (Col. 33, Lines 42-56); use of an external device (Col. 16, Lines 53-68); store patient performance information (Col. 4-5, Lines 50-17); memory store telemetry data (Col. 4-5, Lines 50-17, fig. 10, unit 103, 100, 120).

Nappholz does not disclose a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non conformance is determined; Wojcicki discloses a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non conformance is determined (Col. 4, Lines 15-39), in order to have an accurate monitoring system and guarantees that the drug infused into the body of the patient (Col. 4, Lines 3-6).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nappholz to have a nonconformance management module contained within the memory receiving the pump performance data and determining whether the pump is conforming to performance requirements, and determining what action should be taken if non conformance is determined taught by Wojcicki in order to have an accurate monitoring system and guarantees that the drug infused into the body of the patient (Col. 4, Lines 3-6).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Wojcicki et al. (U.S. Patent 5,190,522).

Regarding claim 12:

Wojcicki discloses an implantable drug delivery device having performance data reporting capability comprising in combination: (a) a memory having stored therein pump performance acquisition instructions (Col. 4, Lines 15-39, fig. 1, unit 5, 3) ; (b) at least one nonconformance monitor module for monitoring at least one pump operation variable in accordance with the pump performance

acquisition instructions to produce pump performance data (Col. 4, Lines 15-39); and (c) a non-conformance management module receiving the pump performance data, determining whether the pump is conforming to performance requirements, and determining what action should be taken if non-conformance is determined (Col. 4, Lines 15-39).

Claim Objections

4. Claims 2, 4, 5-8, 13, 14, 26-28 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitation of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: prior art fail to teach the pump performance data is selected from the group consisting of pump reservoir pressure, fluid outlet pressure, propellant pressure, fluid flow rate, battery current drain, motor current drain, motor drive current profile, battery voltage, and physiologic sensor output level; pump manufacturer requirement information; includes a scheduling module for scheduling an appointment to service the device.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

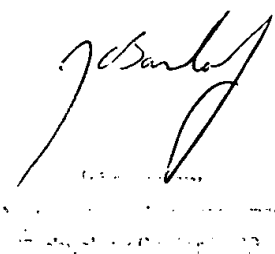
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preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-5841 for regular communications and 703-308-5841 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956. TC2800 FAX Telephone Numbers: 703-872-9306

TC2800 Customer Service FAX - (703) 872-9317

TL



John Barlow
Supervisor
Tung S. Lau, Examiner
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